

**ACTINEL PEDIATRIC- dextromethorphan hbr,guaifenesin,pseudoephedrine hcl solution**  
**Actipharma, Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**ACTINEL PEDIATRIC**

**▯Drug Facts**

***Active Ingredients (in each 5mL tsp)***

Dextromethorphan HBr, 5mg

Guaifenesin, 50 mg

Pseudoephedrine HCl, 15 mg

***Purpose***

Cough Suppressant

Expectorant

Nasal Decongestant

**Uses:**

temporarily:

- relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies
- relieves sinus congestion and pressure, helps decongest sinus openings and passages
- restores freer breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
- suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

**Warnings:**

- A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- **Do not exceed recommended dosage.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.

**Do not:**

- give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor
- use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional condition, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.

**Stop use and ask a doctor if:**

- symptoms do not improve within 7 days or are accompanied by fever

**If pregnant or breast –feeding**, ask a health professional before use.

## ❗KEEP OUT OF REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any sign or symptoms.

### Directions:

- Children 6-12 years, Take 2 teaspoons (10 ml) every 4-6 hours as needed, do not exceed 8 teaspoons in 24 hours, or as directed by a doctor.
- Children 2-6 years, Take 1 teaspoon (5 ml) every 4-6 hours as needed, do not exceed 4 teaspoons in 24 hours, or as directed by a doctor.
- Children under 2 years of age: consult a doctor.

### Other Information

- Tamper Evident: Do not use if inner seal is torn, cut, or opened.
- Store at room temperature 15°- 30°C (59° - 86°F)
- Avoid excessive heat or humidity.

### Inactive Ingredients:

citric acid, flavor, glycerin, methyl paraben, propylene glycol, propyl paraben, purified water, sodium citrate, sucralose

**Contains the same active ingredients as Tusnel® Pediatric\***

**Dextromethorphan HBr**

**COUGH SUPPRESSANT**

**Guaifenesin**

**EXPECTORANT**

**Pseudoephedrine HCl**

**NASAL DECONGESTANT**

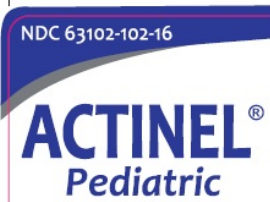
**ALCOHOL FREE**

**COST –EFFECTIVE SOLUTIONS**

Manufactured in the USA for ActiPharma, Inc, Dorado, PR 00646, Tel: (787) 608-0882

**\*Tusnel® Pediatric is a registered trademark of Llorens Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Llorens Pharmaceutical Corp.**

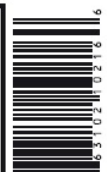
### Packaging



NDC 63102-102-16

**ACTINEL®**  
Pediatric

<b>Purpose</b> Cough Suppressant Expectorant Nasal Decongestant	upper respiratory allergies and passages bronchial passages of productive filled with a cold or	cough persists for more th, or persistent headache, ziness, or sleeplessness curs with asthma or if directed by a doctor use inhibiting (WAO), allergies, or Parkinson's do not know if you pharmacist before giving od pressure, thyroid	l by fever ed, do not exceed 8 d, do not exceed 4 teaspoons	<b>KEEP OUT OF REACH OF</b> Control Center right away, in if you do not notice any	propylene glycol, propyl
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6310210216

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Dextromethorphan HBr  
**COUGH SUPPRESSANT**  
Guaifenesin  
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**NASAL DECONGESTANT**

ALCOHOL FREE

**ActiPharma**  
COST-EFFECTIVE SOLUTIONS

16 FL.oz. (473 mL)

## Drug Facts

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Guaifenesin, 50 mg.....  
Pseudoephedrine HCl, 15 mg.....

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- bothersome mucus, drain bronchial tubes, and make coughs more productive
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### Warnings:

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## DRUG FACTS

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dextromethorphan hbr, guaifenesin, pseudoephedrine hcl solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-102	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	50 mg in 5 mL	
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)		PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	pink	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-102-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2014	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		09/24/2014	

**Labeler** - Actipharma, Inc (079340948)